

Message Text

PAGE 01 STATE 203752
ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-12 ISO-00 OES-09 SIG-03 EB-08
COME-00 /051 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/CE:JHURLEY,JR
EUR/NE:RWOODS
EUR/NE:DGOODMAN
EUR/NE :WNEWLIN
EUR/WE:JDOBBINS
EA/J:HCOCHRAN
EUR/CE:SKLINGAMAN

-----064263 120115Z /62

P 112008Z AUG 78
FM SECSTATE WASHDC
TO AMCONSUL ZURICH PRIORITY
AMEMBASSY OSLO PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY PARIS PRIORITY
AMEMBASSY VIENNA PRIORITY
AMEMBASSY BRUSSELS PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY BONN PRIORITY

UNCLAS STATE 203752

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, SWEL, TBIO, SZ, NO, UK, NL, AU, BE,
JA, GW
SUBJECT: FIRM INITIATED RECALLS OF POTENTIALLY DEFECTIVE
CARDIAC PACEMAKERS (RECALL NUMBERS T103/104/105/8)

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1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALLS:
PRODUCTS INVOLVED - T-103-8 - LITHIUM POWERED CARDIAC PACE
MAKERS, MODELS LI-2F, AND LI-2D, UNIPOLAR FIXED RATE AND
DEMAND PACERS, RESPECTIVELY.
2. T-104-8 - LITHIUM POWERED CARDIAC PACE MAKER, MODEL
LI-3D, UNIPOLAR DEMAND PACER
3. T-105-8 - LITHIUM POWERED CARDIAC PACE MAKER, MODEL
LI-40, DEMAND UNIPOLAR PACER.

4. PRODUCT IDENTIFICATION: ALL PRODUCTS DISTRIBUTED UNDER THE ARCO NUCLEAR PRODUCTS TRADE NAME

5. MANUFACTURER/RECALLING FIRM: ARCO MEDICAL PRODUCTS, RTE 66, LEECHBURG, PA.

6. REASON FOR RECALL: PACEMAKERS MANUFACTURED BY THE FIRM PRIOR TO 10/74 WHICH FAILED A LEAK TEST WERE REWORKED. REWORKING INCLUDED REPLATING THE FEED THROUGH MECHANISM

WITH NICKEL WHICH RESULTED IN EXCESS NICKEL AND A NARROWER INSULATION GAP. THE FIRM TRACED DEFECTIVE UNITS TO A SINGLE TEAM OF TECHNICIANS WHERE INADEQUATE CLEANING OF THE INSULATION GAP LEFT A CHLORINE RESIDUE WHICH CAUSED THE FORMATION OF DENDRITIC NICKEL GROWTHS ACROSS THE INSULATION GAP. THESE DENDRITES PRODUCE AN ELECTRICAL SHORT CIRCUIT WHICH MAY REDUCE THE STIMULATION PULSE AMPLITUDE ENOUGH TO CAUSE SUDDEN INTERMITTANT OR TOTAL LOSS OF CAPTURE. THE FIRM ESTIMATES THAT THIS WILL OCCUR IN LESS THAN 4 PERCENT OF THE UNITS, THIS ESTIMATE IS BASED UPON A MONTHLY FAILURE RATE OF 0.15 PERCENT. THE MAJORITY OF UNITS HAVE 2 YEARS OF WARRANTY REMAINING. UNCLASSIFIED

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7. NO INJURIES OR DEATHS WERE REPORTED; ALTHOUGH 14 PACERS HAVE BEEN EXPLANTED DUE TO FAILURE TO DATE.

8. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED COPY OF FIRMS "URGENT PACEMAKER ADVISORY" LETTER DATED APRIL 17, 1978. A PHYSICIANS LETTER OF SAME DATE WAS ALSO INCLUDED WITH INSTRUCTIONS THAT CONSIGNEES WERE TO FORWARD A COPY OF THE PHYSICIANS LETTER TO THE ATTENDING PHYSICIAN WHERE UNITS HAD BEEN IMPLANTED. THE DECISION AS TO WHETHER TO EXPLANT THE UNIT OR MONITOR THE PATIENT WILL BE LEFT TO THE PHYSICIAN. ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE DIRECTED TO U.S. FIRM.

9. FOREIGN CONSIGNEES AS PROVIDED BY FIRM ARE AS FOLLOWS:

HANS RAHN CO., WEHNTALERSTRASSE 79, CH-8057, ZURICH, SWITZERLAND

LI-2D A3106C VON LARISCH, HANS CHIR. A. KANTONSS, ZURICH

LI-2D A3093C LANZINGER, VIKTORIA CHIR. A. KANTONSS, ZURICH

LI-2D B3806C TOBLER, HANNA CHIR A. KANTONSS, ZURICH

LI-2D B3929C ZIEGLER, LIESEL CHIR. A. KANTONSS, ZURICH

LI-2D B3930C CARTINI, ANTONIO CHIR. A. KANTONSS, ZURICH

LI2D B3940C SCHWENKEL, EMMA CHIR. A. KANTONSS, ZURICH

LI-2D B31076C STAUB, HANS CHIR. A. KANTONSS, ZURICH

LI-2D B3807C BONOMO, OSKAR CHIR. A. KANTONSS, ZURICH

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LI-2D A3100C HITZ, OSKAR CHIR. A. KANTONSS, ZURICH

LI-2D B3805C BERTI, GIOACHINO CHIR. A. KANTONSS, ZURICH

LI-2D B3938C HIRSBRUNNER, HANS CHIR. A. KANTONSS, ZURICH

LI-2F A2030C HANS RAHN CO.

LI-2D B3321C SCHAEERER, MAC KANTONSSPITAL

LI-2D B3863C TINNER, JOHANN KANTONSSPITAL

LI-2D B3843C BINDER, HANNA SPITAL LIMMATTAL

LI-2D B3803C SCHULER, HERBERT CHIR. KANTONSSPITAL ZURICH

LI-2D A3098C WINTSCH, JAKOB MED. POLIKLINIK, ZURICH

LABOR-TEKNIKK, VDM THRANESGT 16, POSTBOX 2683 ST. HANSHAUGEN
OSLO 1 NORWAY

LI-2F A2037C LABOR-TEKNIKK

CHARLES F. THACKRAY LTD., P.O.BOX 171, PARK STREET, LEEDS,
ENGLAND

LI-2D B3696C CHARLES F. THACKRAY LTD.

LI-2D A3067C THOMAS, BERNADETTE BROADGREEN HOSPITAL

LI-2F B2043C CHARLES F. THACKRAY LTD.

LI-2D B3769C BRAILEY, AGNES UNIVERSITY HOSP. OF WALES
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LI-2D A3065C COCKCROFT, WILLIAM WYTHENSHAW HOSPITAL

LI-2D A3070C EVANS, VIOLET P. UNIVERSITY HOSP. OF WALES

LI-2D A3062C MEYLER, SHEILA S. UNIVERSITY HOSP. OF WALES

HILEKES B.V., STARGARDLAAN 13, POSTBUS 202, BOSSUM,
NETHERLANDS

LI-2D A3136C VERHAGEN, DEENEN ST. ELISABETH-ZIEKENHUIS

LI-2D B31033C SCHALKWIJK ST. ELISABETH-ZIEKENHUIS

LI-2D A3151C HILEKES, B.V.

PROMECOME S.A., 68 AVENUE DU GENERAL MICHEL-BIZOT, 75012

PARIS, FRANCE

LI-2D B31070C PROMECOME STE, AN.

LI-2D B31043C PROMECOME STE, AN.

LI-2D B31049C PROMECOME STE. AN.

LI-2D A3159C PROMECOME STE. AN.

LI-2D B31071C PROMECOME STE. AN.

LI-2D B31047C BUYCK, LUCIEN SERVICE DE CARDIOLOGIE

LI-2D B31072C LEFEBURE, LOUISE SERVICE DE CARDIOLOGIE

REAZENT ALLGEMEINE HANDELSGESELLSCHAFT, M.B.H. COK. G.,
THERESIENGASSE II, A-1180 WEIN, AUSTRIA
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LI-2D B3370C STEININGER, SIMON INGENIEURBORO HELMUT
KAIS II. CHIR. UNIVERSITAETSKL

HILLEKES MEDICAL SUPPLIES NV/SA, DE VIBLEGASSTRAT 122, 1820
STROMBEEK-BEVER, BELGIUM

LI-2F B2055C STICHELMANS, EDGARD I.M.C. ANDERLECHT

LI-2D B31010 VINCENT, GILBERT I.M.C. ANDERLECHT

LI-2F B2073C RAIFF, MARTIN I.M.C. ANDERLECHT

LI-2F B2057C VAN DELSEN, PALMYRE I.M.C. ANDERLECHT

LI-2D B3956C EVEILLARD, ANDRE I.M.C. ANDERLECHT

LI-2D B3838C AMBACHTSHEER, C. DRAEMENEN HOSP.

MARUSHO INDUSTRIAL CO. LTD., 11-2, 4 CHOME, GINZA, CHUO-KU,
TOKYO, JAPAN

LI-2D B3716C MARUSHO INDUSTRIAL CO., LTD.

LI-2D B31012C MARUSHO INDUSTRIAL CO., LTD.

LI-2D B3866C MARUSHO INDUSTRIAL CO. LTD.

LI-2D B3855C MARUSHO INDUSTRIAL CO., LTD.

I-2D B31011C MARUSHO INDUSTRIAL CO., LTD.

LI-2D B3955C MARUSHO INDUSTRIAL CO. LTD.
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LI-2D B3714C MARUSHO INDUSTRIAL CO. LTD.

LI-2D B3712C MARUSHO INDUSTRIAL CO. LTD.

ATLANTA BAUER AND CO., DUCKWITZSTRASSE 39, 2800 BREMEN 1,
GERMANY

LI-2D B3468C KROHMANN, VICHOR UNIVERSITAETSKLINIK

LI-2D B3558C GUST, HEINRICH UNIVERSITAETSKLINIK

LI-3D B3014C INGENIEURBORA HELMUT KAIS NURNBERG

LI-2D B3014C INGENIERUBORO HELMUT KAIS NURNBERG

LI-2D B3878C INGENIERUBORO HELMUT KAIS NURNBERG

LI-2D B3874C INGENIEURBORO HELMUTKAIS NURNBERG

LI-2D B3652C INGENIEURBORO HELMUT KAIS NURNBERG

LI-2D B3372C INGENIEURBORO HELMUT KAIS NURNBERG

LI-2D A3251C REITZI, FERDINAND CHIRURGISCHE GIESSEN

LI-2D A3160C KAMPFER, HAUS CHIRURGISCHE GIESSEN

LI-2D B3645C METZ, HEINRICH MED. UNIVERSTATSKLINIK MARBURG

LI-2D B3837C LECHNER, OTTO MED. UNIVERSITAETSKLINIK
FREIBURG

LI-2D B3775C BOAM, ELISABETH KRANKENANSTALTEN
NUERNBERG

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LI-2D A3287C MESSTHALER, BABETTE KRANKENANSTALTEN
NUERNBERG

LI-2D B3844C KUANKIN, ANNA KRANKENANSTALTEN
NUERNBERG

LI-2D B3441C VANHUSEN, NORBERT UNIVERSITAETSKLINIK

LI-4D B4019C VOGSFELD, M. UNIVERSITAETSKLINIK

LI-2D A3185C GUNTHER, BEATE UNIVERSITAETSKLINIKEN

LI-2D B31030C VAIFER, H. UNIVERSITAETSKLINIKEN

LI-2D A3118C WEGENER, KARL-DIETER UNIVERSITAETSKLINIK

LI-2D B3387C WALTHER, WILHELM CHIRURGISCHE GIESSEN

LI-2D A3085C VELTEU, HERMANN CHIRURGISCHE GIESSEN

LI-2D B3836C LOYAL, K. CHIRURGISCHE GIESSEN

LI-2D A3077C KREMER, HIEROUYMUS CHIRURG. UNIVERSITAETSKLI
MARBURGLI

LI-2D A3110C LOWER, HEINRICH CHIRURG. UNIVERSITAETSKLI
MARGURG

LI-2D B3777C MARCH, MARIANNE CHIRURGISCHE GIESSEN

LI-2D B3908C SCHWEICH, ELISABETH UNIVERSITAETSKLINIK

LI-2D B3910C KIRCH ELISABETH UNIVERSITAETSKLINIK
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LI-2D B3871C HOLTEJE, OTTO A.K. ST. GEORGE

LI-2D B3877C KALLISCH, ERICH CHIRURGISCHE GIESSEN

LI-2D A3276C PENQUITT, WERNER CHIRURG. UNIVERSITAETSKLI
MARBURG

LI-2D A3114C PAFFE, HERIBERT CHIRURG. UNVIERSITAETSKLI
MARBURG

LI-2D A3238C FUHRMANN, SOPHIE CHIR. UNIVERSITAETSKILINIK
FRANKFURT

LI-2D A3190C RABE, NELLY CHIR UNIVERSITAETSKILINIK
FRANKFURT

LI-2D B3875C SCHRIDDE, KURT CHIRURGISCHE GIESSEN

LI-2D A3198C RASCH, ERICH CHIRURGISCHE GIESSEN

LI-2D A3237C SCHMIDT, FRANK CHIRURGISCHE GIESSEN

LI-2D A3076C LORKEN, ARNOLD CHIRURGISCHE GIESSEN

LI-2D B3872C SCHWENK, PAUL A.K. ST. GEORG

LI-2D B3893C BOLL, RICHARD A.K. ST. GEORG

LI-2D B31051C HAASE, LIESELOTTE A.K. ST. GEORG

LI-2D B3870C BEKKER, GREVE A.K. ST. GEORG

LI-2D B3479C LUDWIG, RICHARD CHIRURGISCHE GIESSEN

LI-2D B3765C SCHMITT CHIRURGISCHE GIESSEN
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LI-2D B3763C HAN, GUSTL CHIRURGISCHE GIESSEN

LI-2D A3241C AURAND, WALTER CHIRURGISCHE GIESSEN

LI-3D B3018C MICKEL, FRIEDRICH CHIRURGISCHE GIESSEN CHRISTOPHER

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<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 26 sep 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: EQUIPMENT, MEDICAL CARE, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 11 aug 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE203752
Document Source: ADS
Document Unique ID: 00
Drafter: DHEW/FDA: JRWEINROTH, M.D.:VO
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Expiration:
Film Number: D780329-0911
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t197808122/baaazms.tel
Line Count: 356
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Litigation Codes:
Litigation History:
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Message ID: 3bd2f759-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
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Review Content Flags:
Review Date: 29 mar 2005
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Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
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Review Withdrawn Fields: n/a
SAS ID: 1588136
Secure: OPEN
Status: <DBA CORRECTED> jms 970825
Subject: FIRM INITIATED RECALLS OF POTENTIALLY DEFECTIVE CARDIAC PACEMAKERS (RECALL NUMBERS T103/104/105/8)
TAGS: EIND, ETRD, TBIO, AU, BE, NL, NO, SZ, UK, OGEN, SWEL
To: ZURICH OSLO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/3bd2f759-c288-dd11-92da-001cc4696bcc
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Declassified/Released
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20 Mar 2014
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